

CLAIMS

1.- Method to obtain an immunotherapeutic agent that contains cell wall fragments from a virulent *Mycobacterium tuberculosis*-complex (MTB-C) strain, such method being characterized in that it includes the following steps:

- 5 - culture of the virulent MTB-C strain for a period of three weeks or longer and, then,
- homogenization of the cell culture in the presence of a non-ionic tensioactive compound.

10 2.- Method according to claim 1 characterized in that the culture period ranges from 3 to 4 weeks.

3.- Method according to claims 1 or 2 characterized in that the non-ionic tensioactive compound is selected among the group of alcyphenol ethoxylat group and ethoxylated sorbitan esters.

15 4.- Method according to claim 3 characterized in that the non-ionic tensioactive compound is selected among octylphenol ethoxylat compounds.

5.- Method according to claim 4 characterized in that the non-ionic tensioactive compound is selected among octylphenol ethoxylat with 7-8 mol of ethylene oxide.

20 6.- Method according to claims 1 to 5 characterized in that homogenization is carried out in a buffer medium with a neuter pH.

7.- Method according to claims 1 to 6 characterized in that it further includes these steps:

- separating the non-fragmented cells and the solubilized compounds by centrifugation,
- 25 - chemically and physically treating the fraction with the cell wall fragments in order to inactivate all possible remaining virulent strain cells, and
- desiccating the immunotherapeutic agent obtained by lyophilization.

8.- Immunotherapeutic agent obtained by a method according to any of the claims 1 to 7.

30 9.- Pharmaceutical composition that contains the immunotherapeutic agent of claim 8.

10.- Pharmaceutical composition according to claim 9, comprising the immunotherapeutic agent in the form of liposomes.

11.- Use of the immunotherapeutic agent of claim 8 to prepare a drug for the combined treatment of tuberculosis in association with other drugs.

12.- Use according to claim 11, characterized in that the drugs are isoniazid and/or rifampicin.